510(k) Summary

Summary of Safety and Effectiveness

Applicants Name and Address

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Applicants Contact Person

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Date the Summary was prepared

September 29, 2008

Device Name

Trade Name:	Fourth Gas Module with CO_2 for Primus US "Apollo"
Common Name:	Anesthesia machine

Classification

Regulation No.	Device	Product Code
868.5160	Gas Machine – Anesthesia	73BSZ

Legally marketed device to which Substantial Equivalence is claimed

Aestive/5 Anesthesia System	GE Datex-Ohmeda, USA
Ohmeda Excel 3000 Anesthesia System	Ohmeda, USA

Description of the Device

The Fourth Gas Module provides an optional mechanical means of delivering carbon dioxide (CO_2) into the fresh gas coming from the gas mixer of the anesthesia machine Primus US "Apollo".

The Fourth Gas Module consists of a means of flow and pressure control for CO_2; a color-coded control knob; a means of flow and pressure measurement for CO_2; a means to mount a CO_2 E-size cylinder; and an enclosure for the various components.

The Fourth Gas Module has been verified to provide the Primus US "Apollo" anesthesia workstation (K042607) with a means of delivering carbon dioxide as a medical gas.

Intended Use

The Primus US "Apollo" is indicated as a continuous flow anesthesia system. The Primus US "Apollo" may be used for manually assisted, or automatic ventilation, and delivery of gases (O_2, N_2O and CO_2 – in combination with the CO_2 module [i.e. Fourth Gas Module]), anesthetic vapor, and monitoring of oxygen and CO_2 concentrations, breathing pressure, respiratory volume, and anesthetic agent identification and concentration. Federal law restricts this device to sale by or on the order of a physician.

Substantial Equivalence

The Fourth Gas Module with CO_2 for Primus US "Apollo" is substantially equivalent to the following devices:

DEVICE	510(k) NUMBER
Aestiva/5 Anesthesia System	K000706
Ohmeda Excel 3000 Anesthesia System	K973896

The Fourth Gas Module with CO_2 for Primus US "Apollo" provides, as does the Aestive/5 or the Excel 3000, a mechanical means of delivering CO_2 into the fresh gas coming from the anesthesia machine. The Fourth Gas Module is optionally available right from the manufacturer or available as an upgrade. The ambient conditions of the devices differ slightly, but remain comparable.

Like its predicate Aestiva/5 or Excel 3000, the Fourth Gas Module receives carbon dioxide gas from an externally mounted gas cylinder equipped with a pressure regulator and adds it to the anesthetic gas coming from the mixer of the anesthesia machine. As a means to prevent hypoxic gas mixtures, the Fourth Gas Module for Primus US "Apollo" provides an ORC function as does the Aestive/5.

The technical characteristics of the Fourth Gas Module with CO_2 for Primus US "Apollo" do not raise new questions regarding safety or effectiveness. Furthermore, the labeling provides similar information as the predicate device.

Information provided in the 510(k) Premarket Notification supports the determination of substantial equivalence. Design, development, verification and validation of the device was performed in accordance with FDA regulations and guidance and company internal standards. The testing and analysis of results provide assurance that the device meets its specifications and is safe and effective for its intended use.

In summary, Draeger Medical AG & Co. KG has demonstrated that the Fourth Gas Module with CO_2 for Primus US "Apollo" is safe and effective. It is considered to be substantial equivalent to currently marketed predicate devices which have been previously cleared by the FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 8 2008

Dr. Karin Luebbers
Senior Manager Regulatory Affairs
Dräger Medical AG & Co. KG
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Luebeck
GERMANY 23542

Re: K081447
Trade/Device Name: Fourth Gas Module with CO_2 for Primus US "Apollo"
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas Machine for Anesthesia or Analgesia
Regulatory Class: II
Product Code: BSZ
Dated: September 30, 2008
Received: October 2, 2008

Dear Dr. Luebbers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Fourth Gas Module with CO_2 for Primus US "Apollo"

Indications for Use:

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K081447

Prescription Use ___x____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)